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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/640,987 | 08/14/2003 | David I. Shapiro-Ilan | 0019.03 | 9199 |

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EXAMINER

FERNANDEZ, SUSAN EMILY

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| ART UNIT | PAPER NUMBER |
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1651

DATE MAILED: 03/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------|-------------------------------------|--|
| Office Action Summary | Application No. 10/640,987 | Applicant(s) SHAPIRO-ILAN ET AL. | |
| | Examiner Susan E. Fernandez | Art Unit 1651 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) 2,4,5,7,9 and 10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,6,8 and 11-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>9/29/03</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 10-14 following the first instance of claim 10 have been renumbered as claims 11-15.

Claims 1-15 are pending.

Election/Restrictions

Applicant's election with traverse of the species of *Metarhizium anisopliae* having the identifying characteristics of *Metarhizium anisopliae* NRRL 30594 and the species of pecan weevils in the reply filed on February 22, 2006, is acknowledged. The traversal is on the ground(s) that a search for a method for controlling insects utilizing an effective insect biopestical amount of the claimed composition where the insects are pecan weevils would simultaneously encompass a search for any insect controlled by such a method. Moreover, applicant asserts that there would be no serious burden on the examiner to search for the various insects since a search for one insect could be expected to be found in the same reference as that disclosing another insect. This is not found persuasive because references such as Gottwald et al. (Environmental Entomology, 1973, 12(2): 471-474) and Tedders et al. (Journal of Economic Entomology, 1973, 66(3): 723-725) discuss the biocontrol of pecan weevil without discussing the biocontrol of other insects, including diaprepes root weevil, fall armyworm, and fire ant.

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The requirement is still deemed proper and is therefore made FINAL.

Claim 2, 4, 5, 7, 9, and 10 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected species, there being no allowable generic or linking claim.

Claims 1, 3, 6, 8, and 11-15 are examined on the merits to the extent they read on the elected subject matter.

Deposit of Microorganisms

It is noted that claims 1, 3, 6, 8, and 11-15 recite a specific organism, *Metarhizium anisopliae* NRRL 30594. While this raises an issue with respect to enablement under 35 U.S.C. § 112, first paragraph, it appears that the microorganism is publicly available without restriction (page 9 of the specification). The microorganism is therefore considered to be publicly available, unless applicant indicates otherwise. Should applicant become aware of any information to the contrary during the prosecution of this case, applicant must disclose such information to the office.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 6, 8, and 11-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Specifically, the claims recite a biopesticidal composition and its use in controlling any and all insects. Thus, the claims encompass the control of numerous species of insects for which no written description has been provided. Moreover, the sole examples using the biopesticidal composition as claimed do not provide a representative sample of the control of all insects encompassed by the claims, given the huge variation in insects encompassed by the current broad claim language. Instead, the examples in the specification are drawn to the use of biopesticidal compositions comprising the *Metarhizium anisopliae* NRRL 30594 strain being tested on four insects: pecan weevil (page 13), diaprepes root weevil (page 16), fall armyworm (page 16), and fire ants (page 16). Because the claims encompass a multitude of insects which were neither contemplated nor disclosed by the as-filed disclosure, it is clear that applicant was not in possession of the full scope of the claimed subject matter at the time of filing.

Claims 6, 8, and 11-15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for biopesticidal compositions comprising *Metarhizium anisopliae* NRRL 30594 for controlling pecan weevil, diaprepes root weevil, fall armyworm, and fire ants, and methods of controlling these insects with said biopesticidal compositions, does not reasonably provide enablement for biopesticidal compositions comprising *Metarhizium*

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anisopliae NRRL 30594 for controlling any and all insects, and methods of controlling any and all insects with said biopesticidal compositions. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Specifically, as discussed above with respect to the issue of written description, the claims recite biopesticidal compositions and their use in controlling any and all insects. The claims therefore encompass the control of numerous species of insects for which no written description has been provided. However, the sole examples provided in the as-filed disclosure are drawn to the control of pecan weevil, diaprepes root weevil, fall armyworm, and fire ants. Given the huge variation in physiology, biological needs, and sensitivities of the species of insects encompassed by the current broad claim language, the skilled artisan would not expect to be able to apply the disclosed biopesticidal composition to any and all insects encompassed by the current claim language. Thus, with the exception of control of pecan weevil, diaprepes root weevil, fall armyworm, and fire ants, and in view of the lack of any specific guidance with respect to the efficacy of the disclosed biopesticidal compositions in control of the wide range of insects encompassed by the claims, the skilled artisan would expect to have to undertake a trial and error process to determine which of any and all insects encompassed by the claims would be controlled by the application of biopesticidal compositions comprising *Metarhizium anisopliae* NRRL 30594 disclosed in the instant application. Such a trial and error process clearly amounts to undue experimentation.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3, 6, 8, and 11-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 3, 6, and 8 are rendered indefinite by the recitation "identifying characteristics." It is unclear what would be considered identifying characteristics of a particular strain of *Metarhizium anisopliae*. The identifying characteristics could even be considered characteristics that are in common with all *Metarhizium anisopliae* organisms, all fungi, or all organisms. Thus claims 1, 3, 6, 8, and 11-15 are rejected under 35 U.S.C. 112, second paragraph.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3, 6, 8, and 11-15 are rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Gottwald et al. (Environmental

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Entomology, 1973, 12(2): 471-474) or Tedders et al. (Journal of Economic Entomology, 1973, 66(3): 723-725).

The Gottwald reference discloses a strain of *Metarhizium anisopliae* in the form of an inoculum, thus in the form of a biologically pure culture of the fungus strain. See page 471, second column, second paragraph. The inoculum of *M. anisopliae* was applied around the base of pecan trees, and adult pecan weevils passed over the inoculum. Thus, the inoculum was applied to the insect, the plant, area, and substrate infested with the insect. The inoculum served as a biopesticidal composition since adult pecan weevils which were exposed to the inoculum had a greater mortality than weevils which had not be exposed to *M. anisopliae* (page 472, second column, second paragraph and Figure 1). Additionally, Gottwald et al. points to the Tedders reference, wherein *M. anisopliae* was shown as a biopesticidal composition because of the high mortality rate achieved when exposing pecan weevil larvae to *M. anisopliae* (page 471, first column).

Specifically, the Tedders reference discloses isolates of *M. anisopliae* (page 723, first column, last paragraph), thus teaching biologically pure cultures of *M. anisopliae*. Pecan weevil larvae were placed on agar plate cultures of the *M. anisopliae* isolates (page 723, second column, third paragraph), and the isolates were shown to have resulted in increased mortality compared to the control of the experiment (see Table 1 and 2 on page 724). Thus, the isolates are considered to be biopesticidal compositions for controlling pecan weevil. Furthermore, experiments were performed wherein isolates were introduced to tiles placed in the ground beneath a pecan tree (page 724, first column). Larvae were placed in each tile, and it was found that great weevil larvae mortality was achieved with these experiments. Thus, control of pecan weevil larvae was

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achieved by applying the isolates to the area or substrate infested with the insect. Since the larvae are placed on the tile, the fungus is also applied to the larvae. Moreover, since pecan weevil larvae is controlled, adult pecan weevil is also controlled, since a reduction in larvae results in a reduction of the development of larvae into adult weevil.

The strains of *M. anisopliae* appear to be identical to the presently claimed strain, based on the fact that the prior art strain is a member of the same species and has a biopesticidal effect on pecan weevil. Consequently, the claimed strain and its use in controlling pecan weevil, in the forms of adults and larvae, appears to be anticipated by the references.

However, even if the Gottwald and Tedders strains and the claimed strain are not one and the same and there is, in fact, no anticipation, the strains disclosed by the references would, nevertheless, have rendered the claimed strain obvious to one of ordinary skill in the art at the time the claimed invention was made in view of the fact that the references disclose the members of the same species as that claimed, and that each of the strains have a biopesticidal effect on pecan weevil. Thus, the claimed invention as a whole was clearly prima facie obvious especially in the absence of sufficient, clear, and convincing evidence to the contrary.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan E. Fernandez whose telephone number is (571) 272-3444. The examiner can normally be reached on Mon-Fri 8:30 am - 5:00 pm.

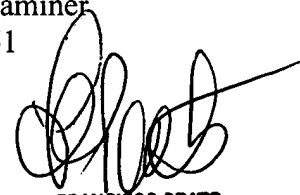
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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